JUN 2 0 2012

510(k) Summary

Contact:	Richard Deslauriers, M.D. CEO, Qualgenix (203) 982 – 4239
Device Trade Name:	Qualgenix Blue Mountain Cervical Plate
Manufacturer:	Qualgenix LLC 1 Jack's Hill Road (Unit 3E) Oxford, CT 06478
Date Prepared:	May 5, 2011
Common Name:	Spinal Fixation Device
Classification:	21 CFR §888.3060; Spinal intervertebral fixation orthosis
Class:	II
Product Code:	KWQ
Indications For Use:	The Qualgenix Blue Mountain Cervical Plate is intended for anterior screw fixation at the vertebral bodies of the cervical spine (C2-C7). Qualgenix Blue Mountain Cervical Plate is indicated for use in temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain in discogenic origin of the disc confirmed by patient history and radiographic studies with degeneration of the disc), spinal stenosis, spondylolisthesis, deformity (defined as kyphosis, lordosis, and scoliosis), trauma (including fractures), tumors, pseudoarthrosis, and/or failed previous fusions. This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. The device is intended for anterior cervical intervertebral body fusions only.
Device Description:	The Qualgenix Blue Mountain Cervical Plate is a system that includes titanium alloy (ISO 5832-3) plates and screws that are intended to stabilize the spine during the interbody fusion process.

Predicate Device(s): The Qualgenix Blue Mountain Cervical Plate was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials used.
The Blue Mountain Cervical Plate is substantially equivalent to the following predicate devices: Synthes Anterior CSLP System (K000742); Aesculap ABC Cervical Plate (K974706, K000486); Theken Tether (K010466); DePuy DOC (K982443); Medtronic Orion (K042235); Medtronic Atlantis (K993855); Medtronic Zephir (K030327, K994239); EBI Anterior Cervical Plate (K001794); Spinevision C^3 System (K012881); and X-Spine Spider Cervical Plate (K052292).

Performance Standards: Testing performed on this device indicates that the Qualgenix Blue Mountain Cervical Plate is substantially equivalent to predicate devices. Testing per ASTM F1717-10 included static compression bending, dynamic compression bending, and static torsion.

Conclusion: Comparisons of device indications, intended use, design, and performance were made to predicate devices in order to determine substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 20 2012

Qualgenix, LLC
% Dr. Richard Deslauriers
CEO
1 Jack's Hill Road, Unit 3E
Oxford, Connecticut 06478

Re: K112809
Trade/Device Name: Blue Mountain Cervical Plate
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: May 13, 2012
Received: May 15, 2012

Dear Dr. Deslauriers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112809

Device Name: Qualgenix Blue Mountain Cervical Plate

The Qualgenix Blue Mountain Cervical Plate is intended for anterior screw fixation at the vertebral bodies of the cervical spine (C2-C7). The Qualgenix Blue Mountain Cervical Plate is indicated for use in temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain in discogenic origin of the disc confirmed by patient history and radiographic studies with degeneration of the disc), spinal stenosis, spondylolisthesis, deformity (defined as kyphosis, lordosis, and scoliosis), trauma (including fractures), tumors, pseudoarthrosis, and/or failed previous fusions.

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Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112809